K131687

medCOMP

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Section 5 510(k) SUMMARY Traditional 510K

A. **Submitter Information:**

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x2271 Fax: (215) 256-9191
Contact:	Jessica Leo Regulatory Associate
Date Prepared:	June 7, 2013

AUG 16 2013

B. **Trade Name:** Medcomp® Pro-Line®CT Power Injectable CVC

Common Name:	power injectable central venous catheter
Classification Name:	Long Term Intravascular Catheter (80 LIS)
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section:	880.5970
Class:	II

C. **Predicate Devices:**

K092547, Medcomp® Pro-PICC®CT
K121094, Medcomp® Vascu-PICC and Midline Catheters
K093309, Medcomp® Pro-Line™ CT Power Injectable CVC
K123617, Medcomp® Pro-PICC®CT

D. **Device Description:**

The Pro-Line®CT Power Injectable CVC triple lumen is an open-ended triple lumen catheter designed for power injection through one designated lumen. The power injectable central venous catheter is comprised of a soft radiopaque polyurethane material. The lumen has a reverse taper design and is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration. The designated 17ga. power injectable extension line and clamp material are purple in color to differentiate it from the clear 19ga. non-power injectable extensions. The purple lumen identifies it as a power injectable catheter. The center extension is also printed with the words power injectable. The I.D. Ring within the clamp on the power extension contains information regarding checking for blood return and flushing along with rate of infusion for power injection.

The catheter has a usable length of 60 cm with numerical markings every 5 cm and depth markings in 1 cm increments. Stylet and adaptor sideport are provided to assist in catheter insertion.

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The catheter is packaged sterile with the necessary accessories to facilitate catheter insertion.

E. **Indications for Use:**

The Medcomp® 6F Triple Pro-Line® CT Power Injectable CVC is indicated for short or long term access to the central venous system. It is designed for administering I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal, allows for central venous pressure monitoring and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec.

F. **Comparison to Predicate Devices:**

The Pro-Line®CT Power Injectable CVC is substantially equivalent to the predicate devices in terms of intended use, anatomical location, basic design, materials, performance, labeling, manufacturing process and method of sterilization.

G. **Bench / Performance Data:**

Performance data for the Pro-Line®CT Power Injectable CVC demonstrates that this device is substantially equivalent to the legally marketed device.

Performance testing of the proposed device was conducted in accordance with applicable international standards and along with internal engineering protocols.

The results of these tests in conjunction with the substantial equivalence claims effectively demonstrate the proposed devices are equivalent to the predicate devices.

H. **Biocompatibility:**

Testing for all materials used for the Pro-Line®CT Power Injectable CVC has been submitted in previously cleared Medcomp devices. All biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993.

I. **Technological Characteristics:**

Technological similarities between the proposed device and predicate devices remain the same.

J. **Summary of Substantial Equivalence:**

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate device.

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Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Agust 16, 2013

Medical Components, Incorporated
Ms. Jessica Leo
Regulatory Associate
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K131687
Trade/Device Name: Pro-Line[MCT] Power Injectable CVC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: June 7, 2013
Received: June 11, 2013

Dear Ms. Leo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131687

Device Name: Pro-Line®CT Power Injectable CVC

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: __K131687_____